Appl. No. 09/516,078
Amdt dated April 9, 2003
Reply to Office Action of Oct. 9, 2002

This listing of claims will replace all prior versions, and listings, of claims in the application:

**Listing of Claims:**

Claim 1 (currently amended): A suppository based vaccine delivery system for prophylaxis against or treatment of urogenitally and anorectally transmitted infectious disease in humans and animals, said suppository comprising:

(a) a vaccine or vaccine adjuvant(s) of whole or fractionated viral or other microbial pathogens, or their purified cellular constituents, whether native, mutated, synthetic, cloned or recombinantly-expressed and combinations thereof, that ~~consists of~~comprises nucleic acids, proteins, lipids, ~~other antigenic determinants~~ or combinations thereof capable of producing humoral- or cellular-mediated immunity in humans or animals; and

(b) a suppository base, selected from the group consisting of polyethylene glycol, polysorbate and combinations thereof;

wherein the suppository is adapted to be inserted into the anorectal or urogenital orifice of a human or animal so as to allow the suppository to be in contact with tissues of the anorectal or urogenital orifice to facilitate transfer of suppository material therethrough.

Claim 2 (currently amended): A suppository based vaccine delivery system for prophylaxis against urogenital tract infections in humans, said suppository comprising:

(a) a vaccine or vaccine adjuvant(s) of whole or fractionated viral or other microbial pathogens, or their purified cellular constituents, whether native, mutated, synthetic, cloned or recombinantly-expressed and combinations thereof, that ~~consists of~~comprises nucleic acids, proteins, lipids, ~~other antigenic determinants~~ or combinations thereof capable of producing humoral or cellular-mediated immunity in humans; and

(b) a suppository base, selected from the group consisting of polyethylene glycol, polysorbate and combinations thereof;

wherein the suppository is adapted to be inserted vaginally so as to allow the suppository to be in contact with vaginal mucous membrane to facilitate transfer of suppository material therethrough.

Claim 3 (currently amended): A suppository based vaccine delivery system for prophylaxis against anorectally transmitted infectious disease in humans or animals, said suppository comprising:

(a) a vaccine or vaccine adjuvant(s) comprising whole or fractionated viral or other microbial pathogens, or their purified cellular constituents, whether native, mutated, synthetic, cloned or recombinantly expressed and combinations thereof, that ~~consists of~~comprises nucleic acids, proteins, lipids, ~~other antigenic determinants~~ or combinations thereof capable of producing humoral or cellular-mediated immunity in humans or animals; and

(b) suppository base, selected from the group consisting of polyethylene glycol, polysorbate and combinations thereof;

wherein the suppository is adapted to be inserted rectally so as to allow the suppository to be in contact with the anorectal mucous membrane to facilitate transfer of vaccine or vaccine adjuvant material therethrough.

Claim 4 (currently amended): The suppository based vaccine delivery system of claim 1 wherein the vaccine content or vaccine adjuvant(s) ~~is~~comprises whole cells, or purified constituents ~~or is generated from known genetic information~~ of urogenitally or anorectally transmittable pathogens.

Claim 5 (original): The suppository based vaccine delivery system of claim 1 wherein the vaccine or vaccine adjuvant(s) contents are present in the total amount of 10 to 1000 micrograms.

Claim 6 (original): The suppository based vaccine delivery system of claim 1 wherein the suppository base is comprised of polyethylene glycol and polysorbate.

Claim 7 (original): The suppository based vaccine delivery system of claim 6 wherein the polyethylene glycol suppository base is comprised of about 75% to about 98% by weight polyethylene glycol and about 2% to about 25% by weight polysorbate.

Claim 8 (original): The suppository based vaccine delivery system of claim 6 wherein the polyethylenc glycol has an average molecular weight of about 950 to about 3700.

Claim 9 (currently amended): The suppository based vaccinc delivery system of claim 6 wherein the ~~polyethylene glycol~~ suppository comprises from about ~~70%~~50% to greater than 99% by weight of the suppository base.

Claim 10 (currently amended): Thc suppository based vaccine delivery system of claim 1 wherein the suppository is further comprised of a preservativc selected from the group consisting of thimersal, benzoic acid, benzoic acid derivatives, benzylkonium, benzylkonium chloride, sulfites, quaternary ammonium salts, chlorobutanol and combinations thereof.

Claim 11 (currently amended): The suppository based vaccine delivery system of claim 10 wherein the suppository is further comprised of an emulsifying agent selected from the group consisting of polysorbate, gelatin, methyl cellulose, alginic acid, sodium lauryl sulfate and combinations thereof.

Claim 12 (currently amended): A suppository-based vaccine delivcry system for prophylaxis against urogenitally or anorectally transmitted infections in humans or animals, said suppository comprising:

(a) a vaccine or vaccine adjuvant(s) comprising purificd, mutated, synthetic or genetically engineered constituents of known pathogens of urogenital pathogens, anorectal~~ly~~ pathogens and combinations thereof; and

(b) a suppository base, selected from the group consisting of polyethylene glycol, polysorbate and combinations thereof;

wherein the polyethylene glycol suppository base is comprised of about 75% to about 98% by weight polyethylene glycol and about 2% to about 25% by weight polysorbate, wherein thc polycthylene glycol has an average molecular weight of about 950 to about 3700, and wherein the ~~polyethylene glycol~~ suppository ~~base~~ comprises from about ~~70%~~50% to ~~about~~greater than 99% by weight of the suppository base; wherein the suppository is adapted to be inserted vaginally or rectally so as to allow the suppository to be in contact with mucous membrane to facilitate transfer of vaccine adjuvant(s) material therethrough.

Claim 13 (currently amended): A suppository-based vaccine delivery system for prophylaxis against genitourinary or anorectal tract infections in humans or animals, said suppository resulting from the mixture of:

(a) a vaccine or vaccine adjuvant comprising whole or fractionated viral or other microbial pathogens, or their purified cellular constituents, whether native, mutated, synthetic, cloned or recombinantly expressed, that ~~consists of~~comprises nucleic acids, proteins, lipids, ~~other antigenic determinants~~ or combinations thereof capable of producing humoral or cellular-mediated immunity in humans or animals; and

(b) a suppository base, selected from the group consisting of polyethylene glycol, polysorbate and combinations thereof;

wherein the polyethylene glycol suppository base is comprised of about 75% to about 98% by weight polyethylene glycol and about 2% to about 25% by weight polysorbate, wherein the polyethylene glycol has an average molecular weight of about ~~750~~950

to about 3700, and wherein the ~~polyethylene glycol~~ suppository ~~base~~ comprises from about ~~70%~~50% to greater than 99% by weight of the suppository base; wherein the suppository is adapted to be inserted vaginally or rectally so as to allow the suppository to be in contact with mucous membrane to facilitate transfer of vaccine or vaccine adjuvant(s) material therethrough.

Claims 14-16 (cancelled).

Claim 17 (currently amended): A method for producing an immune response in humans or animals, said method comprising the steps of:

(a) inserting a suppository into an anorectal or urogenital orifice of a human or animal, wherein said suppository comprises a vaccine or vaccine adjuvant(s) material comprised of whole, fractionated viral or other microbial pathogens, or their purified cellular constituents, whether native, mutated, synthetic, cloned or recombinantly expressed, that ~~consists of~~comprises nucleic acids, proteins, ~~other antigenic determinants~~ or combinations thereof capable of producing humoral or cellular-mediated immunity against urogenital or anorectal disease in humans or animals and a suppository base, wherein the suppository base is selected from the group consisting of polyethylene glycol, polysorbate and combinations thereof; and

contacting the suppository with mucosal tissue at and internal to the anorectal or urogenital orifice to facilitate transfer of the vaccine or vaccine adjuvant material therethrough and induce an immune response in the human or animal.

Claim 18 (previously amended): The method of claim 17 wherein the suppository base is comprised of about 75% to about 98% by weight polyethylene glycol and about 2% to about 25% by weight polysorbate.

Claim 19 (currently amended): The method of claim 18 wherein the polyethylene glycol has an average molecular weight of about ~~750~~950 to about 3700.

Claim 20 (currently amended): The method of claim ~~14~~17 wherein the suppository ~~base~~ comprises from about ~~80%~~50% to greater than 99% by weight of the suppository base.